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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,056	01/11/2001	Diane Pennica	GENENT.2827A2	1938
9157	7590	02/20/2004	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			BORIN, MICHAEL L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,056

Applicant(s)

PENNICA ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-11, 15, 16, 18-21 and 96-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-11, 15, 16, 18-21 and 96-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/06/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued examination under 37 CFR 1.114 after final rejection

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/21/2003 has been entered.

Status of Claims

2. Claims 5,6,9-14,17,22-95 are canceled. Claims 96-101 are added. Status of claims 7-11 is not clear. Applicant indicates, on p.6 of the response, that the claims are canceled ("claims 9-14 canceled"); however, the current version of claims includes the claims. Please clarify. For current examination the claims are considered pending. Claims 1-4, 7-11, 15,16, 18-21, 96-101 are pending.

Information Disclosure Statement

3. Applicants' Information Disclosure Statement filed 05/06/2003 has been considered to the best of Examiner's abilities.

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Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1,7,15,16,18-21,96-101 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides having at least 80% degree of identity with polynucleotides encoding protein of SEQ ID Nos. 2 (which is a protein addressed as PRO10282 or Stra6). As described in the specification, the polynucleotide SEQ ID No. 1 (which encodes protein SEQ ID No. 2) is overexpressed in cancer tissues and thus can be used for cancer diagnostics. Polynucleotide SEQ ID No. 1 itself meets the written description and enablement provisions of 35 USC 112, first paragraph. However, the claims as drawn to nucleotide sequences having more than 80% identity to said polynucleotide do not have sufficient description in the specification as

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description of species is insufficient to support a highly variable genus. Applicant is advised that absent factual evidence, a percentage sequence similarity of less than 100% over the entire length is not deemed to reasonably support to one skilled in the art whether the biochemical activity of newly discovered sequence would be the same as that of similar known biomolecule. The effects of changes in the structure are largely unpredictable as to which ones have a significant effect versus not. No sequence information indicating what is the necessary common attribute for the polynucleotides encompassed by the claimed genus to be useful in the detection of cancer are present in the specification. Therefore, sequence similarity result in an unpredictable and therefore unreliable correspondence between the newly discovered sequence and a similar biomolecule of known function or expression. With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. Accordingly, the specification does not provide a written description of the polynucleotide as claimed, and, consequently, of their complement. Note, that

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even though specification indicates that SEQ ID Nos. 2,5 contain open reading frame encoding protein SEQ ID NO:2 or 5, the claims are not drawn to polynucleotides encoding a particular protein. The specification provides insufficient written description to support the genus encompassed by the claim.

Applicant's arguments have been fully considered but were not deemed persuasive for the following reasons.

As was stated previously, the polynucleotide SEQ ID No. 1 (i.e., isolated DNA that encodes protein SEQ ID No. 2), itself, meets the written description and enablement provisions of 35 USC 112, first paragraph. However, Examiner maintains that the claims as drawn to nucleotide sequences having certain % identity to said polynucleotide do not have sufficient description in the specification as description of species is insufficient to support a highly variable genus. Applicant discusses that the protein SEQ ID No. 2 and its variant (SEQ ID No. 4) are described in specification. The claims, however, are not drawn to polynucleotides encoding a particular protein; rather the claims are drawn to a genus of polynucleotides having certain % identity to said polynucleotide encoding protein SEQ ID No. 2. The only polynucleotide specie specifically disclosed (i.e., SEQ ID No. 1 itself) is not representative of the genus because the genus is highly variant. Adequate written description requires more than

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a mere statement. Applicant discusses regions of high homology of protein SEQ ID No. 2; however, no core structure being encoded by the polynucleotide is not claimed. No sequence information indicating what is the necessary common attribute for the polynucleotides encompassed by the claimed genus to be useful in the detection of cancer are present in the specification. Examiner maintains that the specification provides insufficient written description to support the genus encompassed by the claims.

5. Claims 1,7,15,16,18-21,96-101 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleotide sequence of SEQ ID NO:1 (which encodes protein SEQ ID No 2) does not reasonably provide enablement for polynucleotides having at least certain % identity (80 or 99% sequence identity) to polynucleotide encoding protein SEQ ID No. 2.

The breadth of the claims encompasses not only polynucleotides encoding a STRA6 protein (i.e., protein SEQ ID no. 2) but also polynucleotides having at least certain % identity to a polynucleotide encoding protein SEQ ID No. 2.

There does not appear to be sufficient guidance in the specification as filed as to how the skilled artisan would use the various nucleic acids recited in the instant claims. Specification teaches that polynucleotide SEQ ID No. 1 itself is over-expressed

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in cancer tissues and thus can be used for cancer diagnostics. There is no examples, however, of any other polynucleotide similarly over-expressed in cancer tissues. Nor there is guidance on what core structure is required for a polynucleotide similar to polynucleotide SEQ ID No. 1 to be over-expressed.

Further, specification teaches that polynucleotide SEQ ID No. 1 encodes protein SEQ ID No. 2 (i.e., protein addressed as PRO10282 or Stra6). As the instant claims encompass in their breadth *any* nucleic acid with at least 80 or 99% identity to SEQ ID NO:1, such polynucleotides will encode proteins other than protein SEQ ID No. 2 which will have certain similarity in structure. The use of such proteins (as well as polynucleotides encoding them) is not predictable. Thus, Skolnick et al. (Trends in Biotech. 2000; 18(1):34-39) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Finally, it is well known that even a single amino acid differences can result in drastically altered functions between two proteins. Thus it is unpredictable if any

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functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences. In view of the above, it is the Examiners position that with the insufficient guidance and working examples and in view of unpredictability and the state of art one skilled in the art could not use the invention with the claimed breadth without an undue amount of experimentation.

Further, as the specification does not teach core structure necessary for the above utilities, an artisan would not know how to make polynucleotides as claimed. A person of skill in the art would not be able to determine without undue experimentation which of the plethora of nucleic acid sequences encompassed by the instant claims would share the ability of polynucleotide SEQ ID No. 1 of being overexpressed or being able to encode protein having same function as STRA6.

6. Claims 1,7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 1, 7 introduce new matter as they introduce an unsupported specific negative limitation to exclude polynucleotides encoding murine stra6 polypeptides. The examiner has not found *ipsis verbis* support for this negative claim limitation in the specification. Specification does mention exclusion of nucleic acids encoding murine Stra6, but only in regard to

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nucleic acids hybridizable to complement of DNA encoding protein SEQ ID NO.2 (for this reason claims 9-11 are not subject of this rejection). A negative limitation must have basis in the original disclosure. Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff 'd mem., 738 F.2d 453 (Fed. Cir. 1984). MPEP 2173.05 (I) instructs that any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Applicant must cancel the new matter in response to this rejection.

7. Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 1, 7 introduce new matter as they introduce new matter by claiming, in claim 9, that PRO10282 polypeptide encoded by the claimed nucleic acid is at least 100 amino acids in length. Specification does address various fragments of PRO10282 polypeptide on p. 27 (including fragment of at least 100 amino acids in length), but specification does not specifically teach that nucleic acids that hybridizable to complement of DNA encoding protein SEQ ID NO.2 must encode a fragment of not less than 100 residues. The

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examiner has not found *ipsis verbis* support for this negative claim limitation in the specification. Applicant must cancel the new matter in response to this rejection.

Claim Rejections - 35 USC § 102.

8. Rejection of claims 1,7, 9-11 under 35 U.S.C. 102(a) as being anticipated by the sequence of Database GenEmbl, accession number AF062476 is withdrawn in view of amendment of the claims to exclude polynucleotide encoding murine stra6 polypeptide. However, as the latter amendment represents new matter in regard to claims 1,7, the rejection of claims 1,7 will be reintroduced once the new matter is removed from the claim language.

9. Rejection of claims 9-11 remain under 35 U.S.C. 102(a) as being anticipated by the sequence of Database GenEmbl, accession number AAV84436 is withdrawn in view of amendment to the claims requiring that the claimed nucleic acid encodes at least 100 residues of polypeptide SEQ ID No. 2. However, as the latter amendment represents new matter, the rejection will be reintroduced once the new matter is removed from the claim language.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

February 13, 2004

MICHAEL BORIN, PH.D.
PRIMARY EXAMINER

mlb

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.